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TO: See Distribution List

FROM: Martha Lamont, Director
Monitoring Programs Office

SUBJECT: Microbiological Data Program Plan, January through June, 2004

This Program Plan serves as the current Statement of Work for the period January through June 2004 for each State participating in the Microbiological Data Program (MDP). This document also stipulates work assignments for the Federal facility participating in MDP.

I. ADMINISTRATIVE UPDATES

Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent (e.g., due to laboratory or office renovation/relocation). This information is required under the terms of the MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States.

Once the MDP Progress Update and 2002 Data Summary is ready for release, embargoed copies will be distributed to the MDP participants prior to general release and posting to the MDP website.

A. Personnel

Diana Haynes has been selected as Deputy Director of the USDA Monitoring Programs Office (MPO), Manassas, Virginia. As Deputy Director, Ms. Haynes will serve as the Technical Director for the Microbiological Data Program (MDP). Ms. Haynes has been with MPO since 1996 in the capacity of Quality Assurance Officer (QAO). Jo Dyer, Chemist, was recently hired to help with data review. Jo worked previously at the U.S. Geological Survey.

Until the QAO position is filled, quality assurance functions are temporarily assigned to current staff members as follows:

MDP Laboratory Liaisons

California, Ohio, Wisconsin
Colorado, Florida,
Michigan, Washington, AMS National Science Laboratory (NSL)
New York

Terry Cuncell
Shanker Reddy
Donna Dickriede
Jo Dyer

MDP Proficiency Testing

Diana Haynes
Shanker Reddy

MDP Standard Operating Procedures (SOPs)

Donna Dickriede
Shanker Reddy
Diana Haynes

SOP Deviations (MDP and PDP)

Shanker Reddy and Donna Dickriede, microbiologists, and Terry Councell, chemist share MDP responsibilities. Sampling concerns should be directed to Sharon Williams. Dr. Michael Doyle, Regents Professor and Director, Center for Food Safety, University of Georgia, Athens, GA serves as consultant to MPO headquarters in Manassas, VA.

B. Financial/Cooperative Agreements

MDP is being funded through a Continuing Resolution beginning October 1, 2003. Although the MDP Fiscal Year 2004 (FY04) budget has not been signed yet, MDP is expected to receive \$6.21 million, that is, the same amount received in FY03. MDP FY04 Cooperative Agreements will be issued when the budget is signed by the President.

C. MDP Program Meetings

The Federal/State MDP meeting was held December 2-3, 2003 in McClellan, CA. Technical Advisory Committee Members, QAOs and Administrative Officers from each participating laboratory and staff from MPO and USDA Headquarters discussed methods improvement, proficiency testing, administrative issues, and database management. Guest speakers included Dr. Michael Doyle (University of Georgia), Dr. Arvind Bhagwat (ARS, USDA), Dr. Peter Feng (CFSAN, FDA), Dr. Vrinda Nargund (NARMS, CDC), and Dr. Jean-Yves D'Aoust (Health Canada). LeeAnn Johnson (Minnesota Department of Agriculture) presented data comparing *E. coli*/MPN methods.

Quality Assurance Overview

The MDP QA program covers all aspects of data gathering – from sample collection to data reporting. QA protocols for sampling are designed to protect sample integrity from the time of collection to the time of delivery at the testing facilities. QA protocols for testing comprise all laboratory operations from the time of sample receipt to the time data are reported to the MDP central database located in Manassas, Virginia. MDP laboratories guarantee reported results by adherence to strict QA requirements. The QA program is comprised of five elements: 1) Standard Operating Procedures (SOPs); 2) Quality Control (QC) Procedures; 3) Method Validation Procedures 4) Proficiency Testing; and 5) On-Site Reviews.

Proficiency Testing Program

Produce Quality and Safety Laboratory, ARS, Beltsville, MD has been consulted for proficiency testing. Proficiency testing of *E. coli* will be conducted in 2004; scheduling will be determined in consultation with the laboratories.

Standard Operating Procedures (SOPs)

SOPs are posted to the MDP website when distributed to program participants.
<http://www.ams.usda.gov/science/MPO/SOPs.htm>

D. Electronic Transfer of Data

RDE Version Upgrade Installed: An upgraded version of the Web-based Remote Data Entry (RDE) system was installed on October 15, 2003. This new version includes fixes for over 30 identified glitches, primarily in printed reports. This upgrade and all future system modifications will be programmed by the MPO staff. MPO is maintaining a database of all user change requests, including problems and suggestions received by telephone and e-mail.

RDE System Architecture: The reengineered RDE system is a centralized system, where all RDE database files and support software will reside in Washington, D.C. and laboratory users will require only an Internet web browser on the front-end. A stand-alone Sample Information Form (SIF) data entry system for laptop/desktop computers and for PDAs (Pocket PCs) was developed to allow the capture of SIF data electronically by sample collectors. The SIF data entry system can also be used by laboratories to perform off-line data entry of paper SIF information that can then be imported into the central RDE system.

New RDE Secure Web Address: RDE users in the laboratories should be using the SSL (Secure Socket Layer) site address to access the Web-based RDE system. The only difference is the addition of the letter "s" following "http". This SSL technology is used to encrypt all data passed between the user's computer and the central web server.

Legacy RDE System Cut-off: The cut-off date for ending use of the legacy FoxPro-based Remote Data Entry (RDE) system was July 1, 2003. This means that the Web-based RDE system should be used for all samples collected after June 30, 2003.

II. PROGRAM SAMPLING AND TESTING UPDATES

- A. Sampling Changes and Rotations:** Shipping Charts are distributed quarterly to Sampling Managers by MPO.

Sampling Deletions: None

Sampling Additions: None

Sampling Continuations: Celery, leaf lettuce, romaine lettuce, tomatoes, and cantaloupe will continue.

B. Testing

Target Microorganisms

MDP laboratories will continue to test samples for *E. coli* (quantitative testing). After investigation by the Minnesota Department of Agriculture, the *E. coli* MPN Method (MDP-MTH-01) will be revised to incorporate use of LTB-MUG beginning February 1, 2004. MPO plans to investigate methods to target specific *E. coli* classes important to human health.

MDP laboratories will continue to test samples for *Salmonella* (presence or absence) by BAX. On successful completion of validation, use of BAX as the first step in detection of *Salmonella*

in routine samples began October 1, 2003. The VIDAS-*Salmonella* (SLM) method serves as a backup in case of instrument failure; the revision of MDP-MTH-02 will be effective January 1, 2004. MDP-MTH-03 on the *Salmonella* cultural method has been revised to include testing of control organisms and will be effective January 1, 2004.

Samples will be tested for *E. coli* O157:H7 (presence or absence) beginning April, 2004. Analytical and method performance procedures are being developed by MPO and will be distributed to program participants for review and comment.

All MDP laboratories are now equipped with VITEK instruments to confirm the identification of target organisms.

Archival of Isolates

Laboratories began archiving their isolates November 1, 2003 while a centralized location was under consideration. In the near future, the National Science Laboratory, Gastonia, NC will be established as a centralized location for archival of isolates as well as a distribution center for isolates from the laboratories to the reference laboratories. MPO will develop an SOP for an archiving procedure and revise MDP-SHIP-02 as needed. Laboratories will continue to archive isolates and ship directly to reference laboratories until the new and revised SOPs are in place.

Additional Testing by Reference Laboratories

Currently, isolates are shipped from the individual laboratories to reference labs as follows:

E. coli isolates are shipped simultaneously to the ARS laboratory for inclusion in the National Antimicrobial Resistance Monitoring System (NARMS) database and to the laboratory at Pennsylvania State University for testing antibiotic resistance, serotypes, and virulence attributes.

Salmonella isolates are shipped simultaneously to the ARS laboratory for inclusion in the NARMS database, the University of Pennsylvania for serotyping, and to the laboratory at Pennsylvania State University for testing antibiotic resistance.

In the near future, MPO plans the following changes which will be effective only after official directive from MPO.

NARMS & PulseNet: Isolates will be shipped to FDA, Laurel, MD for antimicrobial resistance and pulsed-field gel electrophoresis (PFGE) analyses for inclusion in the NARMS and PulseNet databases, respectively, with the help from CDC. This will be a collaborative effort between CDC, FDA and USDA-AMS.

The reference laboratories for determining serotypes and virulent attributes are under review.

Data Transfer

AMS will transfer data to CDC and FDA on a semi-annual basis.

C. Future Planning

Demonstration of method performance for detecting *Shigella* in produce will be addressed in March 2004. The implementation of screening produce for *Shigella* is planned for late 2004. Demonstration of method performance and the implementation of a *Listeria monocytogenes* procedure are postponed until further notice.